G1.01.Requirement_proposal

Document: G1.01.Requirement_proposal
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Owner: Head of R&D
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1. Responsible

Jens Meder is the contact person for this requirement. The contact person accompanies this requirement over the entire life cycle.

2. Identifier

ARC-Req2_1 : Analyse ecg data

3. Description

3.1. What should be improved/solved with the requirement?

- Analyze a given ecg including all available channels
    - Detect and annotate episodes of Atrial Fibrillation (AF) and Atrial Flutter (AFl) of 30s and more
    - Detect and annotate signal noise and artefacts in each channel
    - Calculate the atrial fibrillation burden (AF Burden) in terms of
        · the longest episode of AF/AFl measured in seconds
        · the percentage of AF/AFl, e.g., 14% for a total of 42s of af in a 300s recording
    - Calculate the Heart Rate Variability (HRV) using root mean square of successive differences (RMSSD) in milliseconds
    - Calculate the signal quality in terms of net time without artefacts or signal noise
    - Calculate the heart rate (exclude noisy areas to avoid measurement errors)
    - Analysis result is uniquely identifiable (without referencing the specific patient)

3.2. Acceptance critera for a solution

- AF was correctly detected and annotated
- Noise was correctly detected and annotated
- Calculated AF burden
- Calculated HRV
- Calculated signal quality
- Calculated heart rate
- Notes for proposal:
    - The Analysis will have a medical purpose. This makes the following steps necessary:
        · More detailed acceptance criteria will be part of the validation plan and clinical evaluation
        · Precise definition is therefore made in the corresponding process activities

4. Exemplary use case

4.1. Use Case ARC-Req2_1-Uc1 (First Use Case)

- Personas
    - Recorded and converted ecg data
- Preconditions
    - ecg contains AF episodes
- Procedure
    - Analyse ecg
- Expected result
    - AF was correctly detected

1. Approval

Approver	Date	Signature
PO		
Requirement Responsible		
R&D		